



8889 '99 APR 20 P2:04



March 31, 1999

Food and Drug Administration Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition 200 C Street, SW Washington, DC 20204

Dear Sirs:

Notice is hereby given pursuant to the requirements of Section 403(r)(6) (21 U.S.C. § 343(r)(6)) of the Federal Food, Drug, and Cosmetic Act and in accordance with the requirements of 21 CFR § 101.93, that Rexall Sundown, Inc. located at 6111 Broken Sound Parkway, N.W., Boca Raton, Florida 33487 has marketed a dietary supplement under the Sundown Herbals brand name bearing the following statement(s) on the label and/or in the labeling:

Ginseng Complex: [It] promotes energy and endurance. As adaptogens, Siberian and Korean Ginseng naturally help your whole body to adjust to stressful physical and mental demands and help to promote endurance. Ginseng helps the body to utilize oxygen, which enhances recovery and maintains endurance. Vitamin B-12 helps maintain iron-healthy blood and metabolize carbohydrates and fat.

To further promote sustained levels, take Sundown Ginseng Complex with Sundown B-Complex and Sundown CoQ-10. B Vitamins are essential for promoting sustained energy levels throughout the day. CoQ-10 is an antioxidant which also plays a critical role in the production of energy in every cell of the body. Sundown Herbal Complex formulas are carefully selected herbal combinations that naturally promote well-being. Ginseng has been prized in the Orient for centuries to promote strength, energy and endurance. Sundown Ginseng Complex combines Siberian and Korean Ginseng with Vitamin B-12 to create an energizing union of Eastern and Western nutritional wisdom.

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The undersigned certifies that the information contained in this notice is complete and accurate and that Rexall Sundown, Inc. has substantiation that the statement is truthful and not misleading. Pursuant to § 101.93 (a)(1), two copies of this notification are enclosed.

Sincerely,

Deborah Shur Trinker

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Vice President of Regulatory Affairs and Assistant General Counsel

Enclosure